

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:**

1-44. (Cancelled).

45. (Currently amended) A method for analyzing persistent immune system cycling to determine when an agent should be administered to a cancer patient suffering from a disease characterized by the production of regulator cells, the method comprising

i) monitoring the patient, or samples obtained therefrom, for at least one of:

- \_\_\_\_\_ a) effector cell numbers and/or activity;
- \_\_\_\_\_ b) regulator cell numbers and/or activity;
- \_\_\_\_\_ c) a molecule associated with the disease, and/or
- \_\_\_\_\_ d) an immune system a marker of immune system activity,

wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,

ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient and identify, based on the marker of immune system activity, when regulator T cell numbers are increasing in the cycle, and

iii) based on the cycling of the immune system, determining when the agent is to be administered to the cancer patient, wherein the agent is to be administered when regulator T cell numbers and/or activity are identified to be increasing in the cycle such that the agent exerts a proportionally greater effect against the regulator T cells than effector T cells, and wherein the agent comprises at least one therapy selected from the group consisting of anti-proliferative drugs, radiation, dsRNA and antibodies, which inhibits the production of, limits the function of, and/or destroys, regulator T cells.

46. (Currently amended) A method of treating cancer in a patient a disease characterized by the production of regulator cells, the method comprising;

i) analyzing immune system cycling by monitoring a patient suffering from the disease cancer, or samples obtained therefrom, for at least one of:

- \_\_\_\_\_ a) number and/or activity of regulator cells;
- \_\_\_\_\_ b) number and/or activity of effector cells;
- \_\_\_\_\_ c) a molecule associated with the disease, and/or

\_\_\_\_\_ d) an immune system a marker of immune system activity,  
wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,  
ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient and identify, based on the marker of immune system activity, when regulator T cell numbers are increasing in the cycle, and  
iii) exposing the patient to an agent to treat the disease, wherein the agent is administered when regulator cell numbers and/or activity are increasing in the cycle, and wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells administering an agent to the cancer patient when regulator T cell numbers and/or activity are identified to be increasing in the cycle based on the understanding of the dynamics of the immune system cycling from step ii) to treat the cancer by decreasing inhibition of the effector T cells by the regulator T cells thereby enhancing cancer cell destruction by the effector T cells in the cancer patient, wherein the agent is selected from the group consisting of anti-proliferative drugs, radiation, dsRNA and antibodies, and wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator T cells.

47. (Cancelled)

48. (Withdrawn) The method of claim 45, wherein the patient is infected with HIV, Hepatitis B virus or Hepatitis C virus.

49. (Previously Presented) The method of claim 45, wherein the immune system marker reflects the number and/or activity of regulator cells, and/or the number and/or activity of effector cells.

50. (Previously Presented) The method of claim 45, wherein the immune system marker is an acute phase inflammatory marker.

51. (Cancelled)

52. **(Withdrawn)** The method of claim 46, wherein the agent is administered about when CD4+CD8- T cells are detected.

53. **(Withdrawn)** The method of claim 46, wherein the agent is administered approximately when CD8+CD4- T cell numbers have peaked.

54. **(Withdrawn)** The method of claim 46, wherein the molecule associated with the disease is an antigen produced by a cancer cell or an infectious agent.

55. **(Withdrawn)** The method of claim 46, wherein the agent is administered approximately when levels of the molecule associated with the disease begin to decrease.

56. **(Withdrawn)** The method of claim 46, wherein the patient is monitored for an acute phase inflammatory marker, and a molecule associated with the disease.

57. **(Cancelled)**

58. **(Previously Presented)** The method of claim 45, wherein the patient is monitored for a period of at least 21 days.

59. **(Previously Presented)** The method of claim 45, the patient is monitored at least about every 3 days.

60. **(Cancelled)**

61. **(Currently Amended)** The method of claim 45, wherein the patient has not been exposed to a treatment for the cancer disease for at least 21 days.

62. **(Previously Presented)** The method of claim 45, wherein the patient is a human.

63. **(Withdrawn - Previously Presented)** A method for analysing immune system cycling to diagnose a disease characterized by the production of regulator cells, the method comprising

- i) monitoring the patient, or samples obtained therefrom, for at least one of:
  - a) effector cell numbers and/or activity,

- b) regulator cell numbers and/or activity,
- c) a molecule associated with the disease, and/or
- d) an immune system marker, and

wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,

- ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient,

wherein cycling of any one of a) to d) indicates the disease is present.

64. **(Withdrawn- Previously Presented)** A method for analysing immune system cycling to determine when a vaccine should be administered to a patient suffering from a disease characterized by the production of regulator cells, the method comprising

- i) monitoring the patient, or samples obtained therefrom, for at least one of:
  - a) effector cell numbers and/or activity,
  - b) regulator cell numbers and/or activity,
  - c) a molecule associated with the disease, and/or
  - d) an immune system marker,

wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,

- ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient, and

- iii) based on the cycling of the immune system determining when the agent is to be administered, wherein the agent is to be administered when regulator cell numbers and/or activity are increasing in the cycle, and wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells.

65. **(Withdrawn- Previously Presented)** A method of treating a disease characterized by the production of regulator cells, the method comprising;

- i) analysing immune system cycling by monitoring a patient suffering from the disease, or samples obtained therefrom, for at least one of:
  - a) number and/or activity of regulator cells,
  - b) number and/or activity of effector cells,
  - c) a molecule associated with the disease, and/or
  - d) an immune system marker,

wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,

ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient, and

iii) exposing the patient to a vaccine to treat the disease, wherein the agent is administered when regulator cell numbers and/or activity are increasing in the cycle, and wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells.

**66-75. (Cancelled)**

76. (New) The method of claim 50, wherein the acute phase inflammatory marker is c-reactive protein.